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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,497	08/20/2001	Elizabeth Sally Ward	UTSD:483USD1	7113

7590 12/15/2003
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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

933,497

Applicant(s)

WARD

Examiner

SOUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/2/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 16-21 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 16-20 is/are allowed.
- ☒ Claim(s) 21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Amendment of 9/2/03 has been entered. Claims 16-21 are pending and under examination. The amendment has entered no new matter.

The amendment has overcome previously stated issues as follows:

The rejection of claims 16-21 under 35 USC 112, 2nd paragraph.

The following rejections of record are maintained or modified as follows:

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As previously stated, applicant was not in possession of the claimed genus of antibodies having an increased serum half-life, when obtained by the process of claim 16.

Applicant has urged that claim 21 is patentable because it is a product by process claim and not a product claim; as such, the process defines the product. Applicant urges (p. 9) that *Amgen Inc. v. Chugai Pharmaceutical Co.* 18 USPQ2d 1016 supports this position.

Examiner finds this unconvincing. It is true that a process of obtaining a compound may define the obtained product precisely. For example, in the addition of an unsymmetrical substance across a double bond of an unsymmetrical alkane, the addition product obtained may be according to Markownikoff's Rule or the opposite thereof. Which of the two products that is obtained is defined by reaction conditions – i.e. by the nature of the synthetic process. The product obtained can be precisely envisioned, if one knows the reaction conditions provide for an addition product according to Markownikoff's Rule or not.

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Instantly, however, the method of claim 16 is merely a general screening method which can result in the isolation of a number of modified antibodies having structures which cannot be envisioned by a mere statement of the overall plan of the screening method. The examiner is correct in rejecting, since this rationale follows that set forth by *In re Deuel* 34 USPQ 1210, in the view expressed by the CAFC concerning product by process claims in light of *Amgen Inc. v. Chugai Pharmaceutical Co.* (see p.1216 col. 1).

Applicant's arguments filed 9/2/03 have been fully considered but they are not persuasive.

Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,277,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous office action.

It is noted that applicant intends to file a disclaimer, once claims are otherwise allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Typed 12/11/03 DAS

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

